

Remarks/Arguments:

Claims 1-15, 25-27, and 35-43 are the pending claims in this application. Claims 1-15, 25-27, 35-40, 42, and 43 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,522,881 to Lentz (Lentz) in view of U.S. Patent No. 6,159,240 to Sparer et al. (Sparer). Claim 41 stands rejected under 35 U.S.C. § 103(a) over Lentz as modified by Sparer further in view of U.S. Patent No. 6,371,982 to Berg et al. (Berg).

The applicant respectfully submits that claims 1-15, 25-27, and 35-43 recite limitations neither taught nor suggested by any of the references, alone or combined, and for the reasons set forth below, respectfully submits that the claims 1-15, 25-27, and 35-43 are patentable. More specifically, the applicant respectfully submits that there is no motivation to combine the teachings of these references, and furthermore that even if they are combined, one does not achieve the claimed invention.

The claimed invention is directed to an implant having improved fixation to a body lumen. Of the pending claims, the independent claims are 1, 25, 35-38, and 41-43, with claims 1, 35-38, and 41 being device claims, and claims 25, 42, and 43 being method for implanting claims. All of the device claims recite a prosthetic component comprising a graft and having a hem formed therein, wherein the hem defines an interior space, and a cord disposed within the interior space for expanding upon absorbing fluid for aiding in fixating the prosthetic component against the body lumen. Similarly, method claims 25 and 43 recite the same step of introducing such a device into a body lumen, while claim 42 recites first compressing such a device into an introducer and inserting the introducer into a body lumen. Claims 25 and 42 recite contacting the cord of the device with fluid to aid in fixating the prosthetic component against the body lumen. Claim 42 recites removing an impediment to a flow of a fluid within the body lumen to the cord to allow the fluid to contact the cord. As described in the specification, this device and method reduces the possibility of downward movement of the implant and forms a better seal to reduce endoleaks. This device and method are neither disclosed nor suggested in any prior art.

As mentioned above, Lentz and Sparer were used to reject all of the claims except for claim 41. Turning first to Lentz, this patent is directed to an implantable tubular prosthesis having integral cuffs. Specifically, Lentz is a device adapted to accommodate stents and relies in part on using cuffs to create a slot for housing stents. To the extent Lentz addresses

Amendment Dated November 20, 2003
Reply to Office Action of September 24, 2003
Expedited Procedure

prosthetic components, it is only concerned with stent insertion into the cuffs and expanding the cuffs to anchor the conduit in the body vessel.

Sparer is relied upon in the Office Action for its teaching of using an expandable cord disposed within an interior space for absorbing fluid and supposedly aiding fixation of a prosthetic component against a body lumen. Sparer, however, is a rigid annuloplasty device that becomes compliant after implantation. In particular, it relates to a flexible, prosthetic device that is sewn to the supportive framework of a weak and dilated heart valve to provide needed support. See Sparer, col. 4, lines 24-32. *References Dura ring
not cited art (prior art)*

In the Office Action, Sparer has been advanced as showing "the use of an expandable cord 32 disposed within an interior space for absorbing fluid for aiding fixation of prosthetic component 30 against body lumen." See Office Action, page 2. Fig. 4, col. 6, lines 14-45 have been cited to support this assertion. Moreover, the motivation advanced for modifying Lentz is to securely position the component 10 within the body lumen. The applicant disagrees with this use of Sparer.

In particular, the cited portion of Sparer merely describes different ways in which a material can be rigid initially then become flexible upon being contacted with a body fluid. The reason for this characteristic in Sparer is to allow for ease of placement of the device while it is rigid and then becoming compliant after implantation so that the device can serve its function of preventing the valve from becoming distended without significantly impeding the natural motion of the valve. See Sparer, col. 4, lines 10-13. Therefore, nowhere does Sparer contemplate aiding fixation of prosthetic component against body lumen as stated in the Office Action and as used to provide some motivation to combine the references. With no motivation to combine the references, no *prima facie* case of obviousness is made, and all of the rejections in this case must be withdrawn. See MPEP § 2143.

There is another reason why one skilled in the art would not have been motivated to use Sparer in the manner suggested by the Office Action. As mentioned above, the primary function of the annuloplasty device of Sparer is to prevent the heart valve from becoming distended (i.e., from extending radially *outward*). On the other hand, the claimed invention achieves the function of "aiding in fixating said prosthetic component against said body lumen." See, e.g., claim 1, line 7. Thus, the claimed invention imparts a radial force in the exact opposite direction compared to the device in Sparer. The device of Sparer is *sewn* to the heart with sutures to keep the device from distending.

Amendment Dated November 20, 2003
Reply to Office Action of September 24, 2003
Expedited Procedure

Stated another way, the object of Sparer is completely opposite to that of the claimed invention. In Sparer, the use of an expandable cord serves to avoid valve distension by minimizing the radially outward force of the component. On the other hand, the claimed invention serves to aid in fixating a prosthetic component to a body lumen by imparting a radial force to the component against the body lumen.

Independent claim 41 stands rejected as obvious based on Lentz as modified by Sparer further in view of Berg. The applicant contends that claim 41 is patentable over these references for the reasons set forth above and for the reasons discussed below.

Berg Motivation

Berg is relied upon in the Office Action for its teaching of a tubular graft with variable porosity/permeability along the length of the graft to enhance the compliance properties of the graft. Berg, however, teaches the distribution of pore quantities and pore size, and Berg relies on barbs to penetrate the surrounding body organ tubing, thereby holding the graft in place. The applicants contend that there is no motivation to combine the teachings of Berg with that of Lentz and Sparer. The Office Action proposes as a motivation to combine the thought "to enable more fluid to be in contact with" the expandable cord. The applicants contend that such reasoning amounts to hindsight. See MPEP § 2141. Only from a review of the present application can one identify such a basis for this motivation to combine.

Many dependent claims stand rejected in this application as obvious based on Lentz as modified by Sparer. The applicant contends that these dependent claims are patentable over these references for the reasons set forth above. In addition, no citation has been provided in the references as to where they disclose or suggest certain limitations introduced by many of the dependent claims. The applicant has reviewed the cited references and has not been able to find any such disclosure or suggestion for certain claim limitations, including those discussed below.

For example, claim 5 recites the cord in a compressed state prior to being contacted with fluid. Claim 6 recites the thickness of the cord in a compressed state being less than a thirty thousandth of an inch. Claim 7 recites the flat ribbon shape of the cord. Claim 8 recites the shape of the cord to be selected from the group consisting of annular, circular, semi-circular, D-shaped, rectangular, octagonal, trapezoidal, triangular, and square. No citations have been provided in the Office Action as to where these features are described in the cited references, and the applicant has not been able to identify any such description. Therefore, the applicant submits that these claims are also allowable by virtue of the limitations which they recite.

Appln. No.: 09/898,936
Amendment Dated November 20, 2003
Reply to Office Action of September 24, 2003
Expedited Procedure

BSI-479US

For the reasons discussed above, the applicant respectfully submits that claims 1-15, 25-27, and 35-43 are in condition for allowance. Early and favorable notification to this effect is respectfully requested.

Respectfully submitted,


Christopher R. Lewis, Reg. No. 36,201
Attorney for Applicant

CRL/bgd

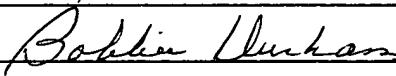
Dated: November 20, 2003

<input checked="" type="checkbox"/> P.O. Box 980 Valley Forge, PA 19482 (610) 407-0700
<input type="checkbox"/> P.O. Box 1596 Wilmington, DE 19899 (302) 778-2600

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 18-0350 of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

November 20, 2003



BGDURHAM_I:\BSI\479US\AMEND-AF.DOC